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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,164	10/21/2002	Matthew P. Patricelli	063391-0202	6075
30542	7590	11/17/2004		
EXAMINER				
CEPERLEY, MARY				
ART UNIT		PAPER NUMBER		
1641				

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/049,164	PATRICELLI, MATTHEW P.	
	Examiner Mary (Molly) E. Ceperley	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 and 8-37 is/are pending in the application.
- 4a) Of the above claim(s) 14-36 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6,8-13 and 37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All . b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/4/03, 9/23/04</u> | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1641

**1)** The following problems should be corrected.

In claim 8, line two, "an" should be --a--.

In claim 11, the sixth line after the formulas, the word "a" (second occurrence) should be deleted.

**2)** Applicant's election of Group I, claims 1-6, 8-13 and 37, in the reply filed on September 07, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 14-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

**3)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**4)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**5)** Claims 1-6, 8-13 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification for the claim 1 steps of "isolating...by binding to a receptor bound to a solid phase... removing unbound proteins, and releasing".

Art Unit: 1641

**6)** Claims 1-6, 8-13 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the term "a functional group specific for one or more active target proteins" that is limited to the functional group being certain types of chemical groups that specifically and chemically bond to the active site of the protein (see paragraph [0042] of the specification) does not provide enablement for all possible "functional groups", for example, "functional groups" having antigen-antibody type specificity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

**7)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**8)** Claims 1-6, 8-13 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** In claim 1, it is unclear what is meant by the term "a functional group specific for one or more active target proteins". It is unclear what kind of specificity is implied by the term "specific for", for example, a functional group which is required to react with a specific amino acid of the protein, a functional group which is required to react with a phosphate group associated with the protein or antigen-antibody type specificity. If a chemical reaction occurs between the "functional group" and the "active target protein", the nature of this reaction is unclear. See also, claim 5 for the unspecified types of reaction of various "functional groups".

**b)** In claim 1, while the "probe" is said to "react with said active target protein", it is unspecified whether the "fluorescent moiety" part of the "probe" or the "functional group" part of the "probe" reacts with the "active target protein". Additionally, it is unclear what kind of binding is involved in the "reaction", for example, antigen-antibody binding, receptor-target binding, covalent binding of a

Art Unit: 1641

chemically reactive functional group to a targeted amino acid (specification, page 20, paragraph [0067]), etc.

**c)** In claim 1, it is unclear what portion of the "probe" is bound by the "receptor", for example, the "fluorescent moiety" or the "functional group".

**d)** Claim 37 is indefinite in not reciting the specificity of the "antibody".

**e)** In claim 11, it is unclear what is meant by the term "or through a link". The type of link and its placement relative to the other parts of the structure are unspecified rendering the claim indefinite. It is also unclear how the "functional group" can be more than one moiety when it is attached to "A" which is defined as "NR, O, S or CH<sub>2</sub>", i.e. there is only one point for attachment of the "functional group" on the "A" moiety.

**f)** In claim 11, it is unclear what is meant to be encompassed by the generic terms "fluorophosphonyl ester", "epoxide", "ethylene alpha to an activating group" and "halogen beta to an activating group". The exact structures meant to be encompassed cannot be determined.

**g)** Claim 12 is indefinite in failing to define the variable "F". The entire fragment "F-P(O)-X-R" would appear to be a functional group rather than "F" *per se* (see the specification at page 25, paragraph [0079]).

**h)** In claim 1, it is unclear what is meant by the term "analyzing a complex protein mixture". It is unclear, for example, if the specific amino acid sequences of each of the proteins in the mixture are to be determined or if some other feature such as the extent of phosphorylation of the proteins is to be determined.

**i)** In claim 11, given stereochemical constraints, it is unclear how "Fl" could be attached at both the 2' and 3' positions of the ribose simultaneously.

**j)** Claim 12 is indefinite and incomplete in not defining the variable "F". There is no antecedent basis in claim 1 for the term "F".

Art Unit: 1641

**9)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**10)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**11)** Claims 1-6, 8-10, 13 and 37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Minden et al (US 6,127,134).

Minden et al describe a method for analyzing proteins which involves the steps of fluorescent covalent labeling of proteins, the separating the labeled proteins and detecting the labeled protein(s) which anticipates the method of instant claim 1. See Minden et al: abstract; col. 5, lines 10-14; col. 6, lines 12-48; col. 9, 3. Protein labeling. The limitations of the remaining claims constitute obvious variations and/or optimizations of variables which are routinely modified in the art and which have not been described as critical to the practice of the invention; for example, the choice of the well known capillary form of electrophoresis (claim 4); for the choice of one of a set of well known equivalent fluorescent dyes (claims 9 and 10) and dyes having absorbance and emission wavelengths in the visible region (claim 8), see Minden et al, col. 5, line 50 – col. 6, line 44.

**12)** Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Bronstein (US 4,978,614).

Art Unit: 1641

Bronstein describes a method for the fluorescent labeling, separating and detecting of proteins which anticipates the method of instant claim 12. See Bronstein: col. 14, F. Electrophoresis; the chromophores of col. 4, line 59 - col. 6, line 19 including Z defined as a phosphate ester (TABLE I, compound (1)) which corresponds to the probe of instant claim 12. Note that instant independent claim 1 requires only the detection of a single "target protein" which is readable on the detection of any of the protein analytes of Bronstein.

**13)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 09, 2004

*Mary E. Ceperley*  
Mary (Molly) E. Ceperley  
Primary Examiner  
Art Unit 1641